Paper No. 35

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte INDER M. VERMA and KEITH R. CAULEY

Appeal No. 1999-1221
Application No. 08/342,242

ON BRIEF

Before SCHEINER, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-4, 7-10, 12-15, and 17, all of the claims remaining in the application. Claim 1 is representative and reads as follows:

1. A method for identifying compounds which modulate signal transduction in cells, said method comprising:

exposing cells to a compound, wherein said cells contain nucleic acids encoding at least one endogenous early response gene and express said gene in the absence of said compound, and wherein the ability of said compound to modulate signal transduction in said cells is unknown; and thereafter

monitoring said cells for changes in early response gene expression levels wherein such changes indicate a compound which modulates signal transduction in said cells, wherein said early response gene is selected from the Myc, Jun, Myb, or Rel families of genes.

The examiner relies on the following references:

Pang 5,418,135 May 23, 1995

Kruijer et al. (Kruijer (1984)), "Platelet-derived growth factor induces rapid but transient expression of the c-fos gene and protein," Nature, Vol. 312, No. 5996, pp. 711-716 (1984)

Kruijer et al. (Kruijer (1985)), "Induction of the proto-oncogene fos by nerve growth factor," Proc. Natl. Acad. Sci., Vol. 82, pp. 7330-7334 (1985)

Sassone-Corsi et al. (Sassone-Corsi), "Regulation of Proto-oncogene fos: A Paradigm for Early Response Genes," Cold Spring Harbor Symposia on Quantitative Biology, Vol. LIII, pp. 749-760 (1988)

Claims 1, 2, 4, 7-10, and 12 stand rejected under 35 U.S.C. § 103 as obvious over either of Kruijer (1984) or Kruijer (1985), in combination with Sassone-Corsi.

Claims 1, 3, 13-15, and 17 stand rejected under 35 U.S.C. § 103 as obvious over Pang, Kruijer (1984), Kruijer (1985), and Sassone-Corsi.

We reverse both rejections.

Background

"Signal transduction" refers to the process of cellular communication by which cells transmit signals within the cell and between cells. Specification, page 1. The specification discloses what Appellants characterize as an "analytical method for identifying compounds which induce and/or inhibit signal transduction in cells." Page 2. The specification states that the disclosed method has the

advantages that it "enables rapid testing of a variety of compounds" and "can be carried out using unmodified cells and/or cell lines, avoiding the need for cell transformation with labor intensive constructs (e.g., reporter constructs) prior to analysis." Id.

Discussion

The examiner rejected the claims as obvious over Kruijer (1984), Kruijer (1985), and Sassone-Corsi (claims 1, 2, 4, 7-10, and 12) or these three references together with Pang (claims 1, 3, 13-15, and 17). According to the examiner, both Kruijer references disclose the use of the claimed method to identify various growth factors and other compounds as inducers of the early response gene fos. Examiner's Answer, pages 5-6. The examiner correctly notes that the disclosures of Kruijer (1984) and Kruijer (1985) are essentially the same as the specification's Examples 2 and 1, respectively. The method disclosed by the Kruijer references differs from that of the instant claims, however, in that the instantly claimed method requires monitoring the expression of a gene other than fos. Specifically, the claimed method requires monitoring a gene "selected from the Myc, Jun, Myb, or Rel families of genes."

The examiner found this deficiency in the Kruijer references to be remedied by Sassone-Corsi. According to the examiner,

> Sassone-Corsi et al. discloses that regulation of *fos* is a paradigm for early response genes, such as myb, myc, rel and jun transcription factors (See Title, col. 1, and Fig. 1, page 749; Fig. 11, page 759). Figure 1 illustrates that a variety of signal transduction pathways lead to induction of *myb*, *myc* and *jun*. The reference further teaches that *fos* and *jun* interact cooperatively to activate

> transcription (page 754-757, col. 1), and that a number of nuclear oncoproteins, such as Jun, Myb, Myc, and Rel respond to signal transduction (Fig. 11, page 759).

Examiner's Answer, pages 5-6. The examiner concluded that it would have been obvious

> to monitor expression of Jun, Myb, Myc, and Rel early response genes in the methods of Kruijer ([1984]) and Kruijer ([1985]) in place of Fos to identify compounds which modulate of [sic] signal transduction with a reasonable expectation of success in view of the relationship between Jun, Myb, Myc, Rel and Fos in signal transduction pathways. The skilled artisan would have recognized that monitoring any of these early response genes would be equivalent to monitoring Fos to identify signal transduction modulators in general, since Sassone-Corsi et al. taught that they shared an equivalent position in signal transduction pathways.

Examiner's Answer, page 6.

We do not agree that Sassone-Corsi would have provided sufficient motivation to practice the method disclosed by the Kruijer references with genes of the Myb, Myc, Jun, or Rel gene families. Sassone-Corsi characterizes fos as a "paradigm for early response genes" (see the title) and teaches that nuclear oncoproteins, including Fos, Myc, Jun, and Rel have "possible involvement . . . in response to signal transduction." Figure 11 (emphasis added). Also, Sassone-Corsi states that nuclear oncoproteins are part of a "complicated network" that responds to external stimuli (i.e., signal transduction). Finally, Sassone-Corsi states that "[t]he challenge in the next few years will be to understand the complicated mechanism of signal transduction." Id.

Sassone-Corsi cannot fairly be said to provide sufficient motivation to those skilled in the art to modify the experiments disclosed by the Kruijer

references by monitoring myb, myc, jun, or rel rather than fos. The "evidence of a suggestion, teaching, or motivation to combine . . . must be clear and particular." In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Sassone-Corsi provides only vague and tentative statements linking fos with the nuclear oncoproteins recited in the claims. These statements fall short of the "clear and particular" evidence of motivation to combine that is required to support a prima facie case of obviousness.

While Sassone-Corsi's disclosure may have motivated a person skilled in the art to conduct general research aimed at elucidating the role of nuclear oncoproteins such as Myc, Jun, and Rel in the process of signal transduction, such general motivation at most makes an invention obvious to try. See In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) ("The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. . . . In others, what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it."). Of course, "obvious to try" is not obviousness under § 103.

Nor does the disclosure of Pang provide the required motivation with respect to claims 1, 3, 13-15, and 17. Pang's disclosure relates to PDGF receptors and identification of antagonists for PDGF receptors. Pang provides

no basis for substituting a gene from the Myb, Myc, Jun, or Rel gene families for the fos gene in the method disclosed by Kruijer.

The references relied on by the examiner do not support a prima facie case of obviousness, and we therefore reverse the rejections.

Other Issues

The claims present an unresolved issue of claim construction that may be relevant to the patentability of the claimed method over the prior art. The issue is not directly relevant to the rejections on appeal, so we do not reach it, but the examiner should clarify the proper construction of the claims on the record in light of the following comments.

The preamble of claim 1 states that it is directed to a "method for identifying compounds which modulate signal transduction in cells." It is well-settled that "a claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." Bell Communications Research Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim

construction because it cannot be said to constitute or explain a claim limitation." Pitney Bowes Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

In the instant claims, it is an open question whether the preamble language ("method for identifying compounds which modulate signal transduction in cells") has any patentable weight. The preamble language might limit the claimed method, for example, if the selection of compounds to be tested would depend on the anticipated effect of the compound on signal transduction. On the other hand, if any compound might have an effect on signal transduction, the preamble language might place no additional limits on the method defined in the body of the claim.

This claim construction issue depends on technical aspects of the disclosed method and therefore we leave its resolution to the examiner. If the examiner is uncertain what weight should be given to the above-quoted language, we remind him that claims are given their broadest reasonable interpretation consistent with the specification. See, e.g., In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

We encourage the examiner, after resolving the claim construction issue, to consider some of the references that are cited by the references relied on in this appeal. We attach copies of two papers that seem particularly relevant. Lamph appears to disclose a method comprising exposing cells that express jun to compounds including cycloheximide and TPA, and monitoring changes in the

expression of jun. See Figure 2. We note that TPA is one of the compounds tested in the specification for its effect on fos expression. See Example 2. Kelly appears to disclose a method comprising exposing cells that express myc to compounds, including PDGF, and monitoring changes in the expression of myc. See Figure 4. We note that PDGF is one of the compounds tested in the specification for its effect on fos expression. See Example 2. The examiner should consider whether Lamph or Kelly, or other prior art disclosures, anticipate the instantly claimed method.

Summary

The cited references do not provide the requisite "reason, suggestion, or motivation" to practice the instantly claimed method and therefore do not support a prima facie case of obviousness. Therefore, we reverse the rejections under 35 U.S.C. § 103. However, we encourage the examiner to consider whether the claims are anticipated by prior art references other than those relied on in the obviousness rejection.

REVERSED

TONI R. SCHEINER Administrative Patent Judge	)
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DEMETRA J. MILLS Administrative Patent Judge	) APPEALS AND
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ERIC GRIMES Administrative Patent Judge	)

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